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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,020	03/16/2001	Robert Charles Downs	P0037US00	9097

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EXAMINER

LILLING, HERBERT J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/810,020

Applicant(s)

DOWNS, ROBERT CHARLES

Examiner

HERBERT J LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 March 2002.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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1. Receipt is acknowledged of the prior art information disclosure statement filed March 10, 2002.

2. Claims 1-58 are pending in this application.

3. Restriction to one of the following inventions is required under 35 U.S.C.

121:

I. Claim 1-31, drawn to a method of performing a plurality of fermentations followed by in the same vessel a further processing of the sample, classified in class 435, subclass 41+.

II. Claims 32-58, drawn to an apparatus comprising a first station and a second station, classified in class 435, subclass 283.1+ depending upon the second apparatus.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process whereby the sample is not retained in the same first station.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

**PROCESS CLAIMS:**

A. Whereby the further processing step is:

- a. centrifugation of the fermented samples in the sample vessels;
- b. aspirating the sample;
- c. sonicating the sample;
- d. washing the sample;
- e. agitating the sample;
- f. lysing cells in the fermented samples;
- g. isolating a product;
  - ga. Column chromatograph;
- h. method employs a robot that tests tens to thousands of variants of a protein;
  - ha. Robot includes a plate handler;
- i. processing steps includes two or more of the above-please specify;

B. Whereby there processing involves:

- aa. no additional further processing step other than above A;
- bb. an additional further processing step of isolating recombinant proteins expressed;

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bba. Crystallizing the isolated sample

bbaa. Analyzing by x-ray crystallography

bbab. Identifying crystals using crystal algorithms;

bbac. Crystals are frozen and analyzed by X-ray diffraction.

C. Whereby the fermentation process includes:

i. attaching a fermentor head to the sample vessels;

ii. attaching a robotic gripper apparatus;

D. Whereby the fermentation process comprises cells or particles containing:

x. prokaryotic cells;

xa. Gene fragment in a vector;

xb. Gene variant in a vector.

y. eukaryotic cells;

ya. Gene fragment in a vector;

yb. Gene variant in a vector.

z. viral particles.

za. Gene fragment in a vector;

zb. Gene variant in a vector.

E. Whereby the fermentation process involves

1. aerobic fermentation;

2. anaerobic fermentation.

**APPARATUS CLAIMS:**

Whereby the second stations comprises:

- a. centrifuge system;
- b. process controller;
- c. robotic gripper;
- d. means for aspirating the samples;
- e. means for sonicating the samples;
- f. means for agitating the samples;
- g. a robot that tests thousands of variants of a protein;
  - ga. Includes a plate handler;
- h. means for performing x-ray crystallography
- i. means for analyzing on an imaging station;
- j. means for identifying crystals with crystal detecting algorithms;
- k. systems contains a X-ray analyzer;
- l. more than one of the above a – k -please specify which additional

species are included in this selection of species l.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 31 are generic to either the process or apparatus claims.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined I or II and election of species appropriate for either Invention I or II with election of one species for each of the A-E groupings for the method claims or one species for the apparatus claims even though the requirement be traversed (37 CFR 1.143).

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7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number is (703) 308-4242 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL  
(703) 308-2034  
Art Unit **1651**  
September 17, 2002

  
Dr. Herbert J. Lilling  
Primary Examiner  
Group 1600 Art Unit 1651